IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

SMITH & NEPHEW, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 02-2873 Ma/A
	)	
SYNTHES (U.S.A.) and SYNTHES-STRATEC, INC.,	)	
	)	
	)	
Defendants.	)	

MEMORANDUM OPINION
FINDINGS OF FACT AND CONCLUSIONS OF LAW

On November 13, 2002, Plaintiff Smith & Nephew, Inc. ("Smith & Nephew") sued the Defendants for infringement of two patents, U.S. Patent No. 5,167,663 ("the '663 patent") and U.S. Patent No. 5,312,406 ("the '406 patent"). The court held a patent construction hearing under Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996), on May 14, 2004, and entered an order construing the disputed patent terms on August 26, 2004. The case was tried discontinuously without a jury, beginning December 6, 2004, and ending March 4, 2005. As required by Rule 52 of the Federal Rules of Civil Procedure, the court sets forth its findings of facts and conclusions of law from that trial.

259

I. Background

Plaintiff Smith & Nephew brings this action for patent infringement against Defendants Synthes (U.S.A.) and Synthes-Stratec, Inc. (collectively "Synthes") under 35 U.S.C. § 1, et seq. Both of the patents in this case, as well as their ancestors, relate to the treatment of femoral fractures through the use of an intramedullary nail which allows for sliding compression.[1] David L. Brumfield filed United States Patent Application No. 947,656 on December 30, 1986. U.S. Patent No. 5,167,663. That application resulted in the issuance of U.S. Patent No. 4,827,917 for a femoral fracture device. Id. Patent Application No. 697,155 was a continuation-in-part of Patent Application No. 337,191 (abandoned), which was itself a continuation-in-part of Application No. 947,656. Id. That application resulted in the issuance of U.S. Patent No. 5,167,663 ("the '663 patent") for a femoral fracture device. Id. Patent Application No. 983,831 was a divisional application of co-pending Patent Application No. 07/697,155. U.S. Patent No. 5,312,406. Brumfield's Application No. 983,831 resulted in the issuance of U.S. Patent No. 5,312,406 ("the '406 patent") for a method of treating an intertrochanteric fracture.[2] Id. Brumfield assigned both of the patents at issue to Smith & Nephew.

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[1] "Medulla" is defined as "bone marrow." Merriam-Webster's Collegiate Dictionary 771 (11th Ed. 2003). An intramedullary nail/rod is one that is used within the marrow cavity of bone.

[2] "Trochanter" is defined as "a rough prominence at the upper part of the femur ..." Merriam-Webster's Collegiate Dictionary 1340 (11th Ed. 2003).

Smith & Nephew asserts infringement of the following claims from the '663 patent:

1. Apparatus for treating fractures of the femur comprising:

a) a hollowed intramedullary rod having a longitudinal axis and a rod sidewall that surrounds a longitudinal bore, said rod having a proximal head and a stem distal thereto, and wherein the stem and a substantial portion of the head are adapted in use for insertion into the narrow canal of a femur;

b) the rod sidewall having a first, generally uniform smaller wall thickness defining the stem, and a second, larger wall thickness defining the head;

c) said head having a first smooth opening extending therethrough in an angled direction relative to the rod is in position within the marrow canal of the femur, the opening is positioned to intersect the longitudinal axis of the rod, and the axis of said opening is directed toward the head of the femur;

d) a first screw for insertion through said first opening in said head and including first and second end portions;

e) said first screw having a threaded surface formed at the first end adapted in use to engage bone tissue of the head and including first and second end portions;

f) wherein said threaded section is spaced from the first opening during use for maintaining continuous sliding contact between said head of said rod and the first screw, to permit sliding compression of the selected fracture.

2. Apparatus as recited in claim 1 which further comprises:

means associated with said rod for preventing rotation of the head of the femur relative to said

first screw.

3. Apparatus as recited in claim 2 wherein:

said head has a second opening extending therethrough in an angled direction relative to the longitudinal axis of said rod, the axis of said second opening being generally parallel with the axis of said first opening; and

said means for preventing rotation comprises a second screw having a threaded end and a smooth surface along the remaining major portion of its length, said smooth surface being adapted in use for sliding contact with said head of said rod through said second opening. ...

5. The apparatus of claim 3 wherein the first and second openings have smooth surfaces that engage corresponding smooth surfaces of the first screw and the rotation preventing means respectively.

U.S. Patent No. 5,167,663, Column 8:4-57.

Smith & Nephew asserts infringement of the following claims within the '406 patent:

1. A method of treating an intertrochanteric fracture of a patient's femur that is located generally between the head of the femur and the intramedullary canal, comprising the steps of:

a) inserting an elongated intramedullary rod having a longitudinal axis into the patient's femur, wherein the rod has a distal stem portion, a head having a first smooth opening extending therethrough in an angled direction relative to the longitudinal axis of said rod such that when said rod is in position within the intramedullary canal of the femur, the opening is positioned to intersect the longitudinal axis of the rod, and the axis of said opening is directed toward the head of the femur;

b) positioning the rod so that the axis of the smooth opening extends across the fracture and into the head of the femur;

c) inserting a first screw through said first opening in said head and including first and second end portions;

d) said first screw having a threaded surface formed at the first end adapted in use to engage bone tissue of the head of the femur;

e) compressing the fracture using the bone screw while maintaining continuous sliding contact between the bone screw and the rod at the smooth opening;

f) wherein said threaded section is spaced from the first opening during use for maintaining continuous sliding contact between said head of said rod and the first screw, to permit sliding compression of the selected fracture; and

g) wherein in step "f" the cross section of the smooth opening closely conforms to the cross section of the screw so that the smooth opening rigidly affixes the screw in a single angular position relative to the rod, along said axis.

2. The method of claim 1 wherein in step "e", the threaded section of the bone screw is spaced away from the opening during compressing of the fracture.

3. The method of claim 1 wherein in step "e", the opening and the smooth surface of the bone screw are each cylindrically shaped. ...

5. The method of claim 1 wherein step "a", the head of the intramedullary rod has a pair of smooth openings that are spaced apart and each opening extending through the intramedullary rod in an angled direction relative to the longitudinal axis of the rod and in step "c", first and second screws are inserted respectively through the openings in the head, each of the screws including first and second end portions, and in step "d", the pair of screws each provide threaded surfaces formed respectively at the first end portion of each screw adapted and used to engage bone tissue of the head of the femur.

6. The method of claim 1 wherein in step "a", the head portion of the rod has a pair of spaced apart, smooth openings extending through the head of the rod in an

> angled direction relative to the longitudinal axis of the rod and one of the openings has a greater diameter than the other of the openings.
>
> 7. The method of claim 6 wherein in step "c", a pair of screws are inserted respectively through the pair of openings in the head, each screw including first and second end portions. ...
>
> 9. The method of claim 1 wherein in step "a", the elongated intramedullary rod has a longitudinal bore surrounded by an intramedullary rod side wall, and the side wall of the rod is thicker at the head than the side wall of the rod at the distal stem.

U.S. Patent No. 5,312,406, Column 7:63-8:36.

Smith & Nephew claims infringement by two of Synthes's products, the Trochanteric Fixation Nail ("TFN") and the Proximal Femoral Nail ("PFN"). The TFN is an intramedullary implant designed to treat fractures of the femur. It consists of an intramedullary nail through which a cross-member known as a Helical Blade is inserted. The intramedullary nail of the TFN includes a wide upper portion and a narrowed lower portion that is designed to be implanted in the medullary canal of the femur. The TFN is available in a number of different versions, according to the length and diameter of the "stem" of the intramedullary nail, with the longer versions having a "fluted" stem resembling the bit of a Phillips head screw driver.[3]

The PFN is also an intramedullary implant designed to treat fractures of the femur. It consists of an intramedullary nail

[3] This analogy is not perfect. The TFN has six outer "points" along the circumference of the stem, where a Phillips screwdriver has only four.

portion that is inserted into the medullary canal of a femur and two lag screws that pass through the intramedullary nail and into the femoral head. The "standard" version of the PFN is 240 mm long, and the "long" PFN is available in lengths of 340mm, 380 mm, and 420 mm. The illustration presented in the PFN Guide does not indicate that the stem of the Long PFN is fluted.

II. Validity

As an affirmative defense, the Defendants argue that the asserted patents are invalid under various legal theories. Because the existence of a valid patent is a necessary precondition to a successful claim of infringement, the court will address the question of validity first. A patent is presumed valid, and the burden of proving otherwise rests solely on the party asserting invalidity. 35 U.S.C. § 282; Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1573 (Fed. Cir. 1985); W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540, 1553 (Fed. Cir. 1983).

A. 35 U.S.C. § 112

Federal law requires that a patent specification "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, precise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112. The

Defendants sought to prove at trial 1) that the application for parent Patent No. 4,827,917 does not sufficiently describe the inventions claimed in the '406 and '663 patents so as to entitle them to its earlier filing date, 2) that the '406 and '663 specifications do not adequately enable one skilled in the art to practice the claimed inventions, and 3) that the '406 and '663 specifications do not set out the best mode for practicing the inventions as contemplated by the inventor. Where a party challenges the validity of a patent under 35 U.S.C. § 112, that party must establish invalidity by clear and convincing evidence. See Ralston Purina, 772 F.2d at 1574; Pennwalt Corp. v. Akzona Corp., 740 F.2d 1573, 1578-79 (Fed. Cir. 1984).

1. Written Description in the '917 Application

On December 30, 1986, U.S. Patent Application Serial No. 06/947,656 was filed, which issued as U.S. Patent No. 4,827,917. (the "'917 application" or "'917 patent," as appropriate). On April 12, 1989, the patentees filed U.S. Continuation-in-Part Application Serial No. 07/337,191 (the "'191 CIP application"), which was a continuation-in-part of the '917 application and which both parties concede is a predecessor to the '663 and '406 patents.

In 1987, the Russell-Taylor Reconstruction Nail ("Recon Nail"), an intramedullary rod with two openings in the head to receive screws that provide sliding compression, was placed on the market for sale, and a technique guide ("Russell-Taylor brochure")

was published describing the use of that device to treat femoral fractures. Synthes contends that the Russell-Taylor brochure and the Recon Nail anticipate the asserted claims in the '406 and '663 patents. Synthes further argues that the '191 CIP application was the first disclosure of those claims in patent documents and that April 12, 1989, is therefore the first date upon which Smith & Nephew can claim priority for the asserted claims.[4]

Because the Recon Nail was on sale, and the Russell-Taylor brochure in publication, more than one year before the '191 CIP application was filed, Synthes argues that the asserted claims are invalid under 35 U.S.C. § 102(b) ("A person shall be entitled to a patent unless ... the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States"). Smith & Nephew contends that the prior '917 application, not the '191 CIP application, first disclosed the claims asserted in this case.

The first paragraph of 35 U.S.C. § 112 provides that "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same ...." For purposes of claiming

[4] The corollary of this argument is that the original '917 application did *not* disclose the patent claims asserted in this case.

priority under a previous patent application, 35 U.S.C. § 120 provides that "[a]n application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States ... shall have the same effect, as to such invention, as though filed on the date of the prior application ...." Thus, the first question before the court affecting the validity of the patent is whether, under 35 U.S.C. § 112, the asserted claims were disclosed in the earlier '917 application.

For purposes of priority under 35 U.S.C. § 112, a specification in a parent patent or patent application adequately describes an invention if it "reasonably convey[s] to one of skill in the art that the inventor possessed the later-claimed subject matter at the time the parent application was filed." Tronzo v. Biomet, Inc., 156 F.3d 1154, 1158 (Fed. Cir. 1998)(citing Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991)).

The abstract of the '917 application describes "*at least a proximal pair of coaxial holes and a distal pair of coaxial holes in the head* of the rod in an angled direction toward the femoral head relative to the longitudinal axis of the rod." ('917 App. at 19)(emphasis added.) Additionally, a description of the preferred embodiments states that "[t]he head 22 includes *at least two pairs* of holes..." (Id. at 8)(emphasis added). The '917 patent which eventually issued contains ten claims, all of which require the head to have "at least a distal pair of head holes and a proximal

pair of holes." U.S. Patent No. 4,827,917, Column 7:49-51. Synthes sought to prove at trial that this language discloses a head that must have at least two pairs of openings. The '917 application does not, according to Synthes, disclose a device, such as that claimed in the '406 and '663 patents, which has only a single pair of openings. Thus, Synthes argues, the '917 application did not reasonably convey to one skilled in the art that the inventor was in possession of a device that contained only one proximal pair of holes.

After careful review of the testimony and documentary submissions, the court concludes that Synthes has not offered clear and convincing evidence that the '917 applicant did not possess an intramedullary rod with a single pair of holes. It is well established that "disclosure of a species may be sufficient written description support for a later claimed genus including that species." Bilstad v. Wakalopulos, 386 F.3d 1116, 1124 (Fed. Cir. 2004). That is especially the case when, as here, there exists a "degree of predictability of technical variations in [the] field of art." Id. at 1126. The prior art submitted with the '917 application contains several devices featuring only one proximal pair of holes, and the ability to treat femoral neck fractures with a device employing one proximal pair of holes was well known.[5] (TX

[5] The court recognizes that recitation of the prior art alone is insufficient to fulfill the written description requirement. See Tronzo, 156 F.3d at 1159. Here, prior art demonstrates the general state and predictability of the art, and unlike the plaintiff in Tronzo, there was no attempt to distinguish as inferior what is now being claimed (the one-pair design). See id.

22, 127; Tr. 268:5-25.)[6] Thus, it can reasonably be assumed that an inventor who discloses a device with two pairs of proximal holes possesses a device with one proximal pair.

A device with two pairs of holes must necessarily contain one pair of holes. Synthes has not shown by clear and convincing evidence that the second proximal pair of holes was so integral to the structure or function of the described invention that the maker of that invention did not also possess a device with a single pair of holes. Synthes concedes that the '917 invention could be used with only one proximal screw and that the second proximal screw was optional. Synthes argues, however, that the '917 application sought to teach away from a single-pair device by stressing the benefits of a "universal" invention. The evidence at trial shows that the universal attributes of the '917 invention lay in its combination of the techniques of intramedullary fixation and sliding compression. The second proximal screw was intended to provide an optional anchor against rotation of the femoral head; it was considered unnecessary in treating the many types of femoral fractures where risk of rotation was nonexistent or minimal. (Tr. 236:12-237:19; 2146:19-2148:1). Further, as of the filing of the '917 application, devices featuring a second or supplementary screw already existed. (Tr. 268:5-25). Thus, the option of using the

[6] For purposes of this order, the court will cite the trial exhibits as "TX" and the transcript as "Tr." As to the prevalence of single-pair femoral devices, if the '917 applicant had sought to distinguish the attributes of a two-pair device from the shortcomings of the single-pair prior art, Smith & Nephew would be precluded from asserting that the '917 specification covers a one-pair device. The court will address that issue below.

second proximal screw was not what rendered the '917 invention "universal" as compared to the prior art.

That the language of the '917 specification speaks of a device containing at least two pairs of proximal holes is not inconsequential. The issue, however, is what the specification would convey to one skilled in the art; the disclosure need not provide in haec verba support for the later-claimed subject matter. See Lampi Corp. v. American Power Products, Inc., 228 F.3d 1365, 1378 (Fed. Cir. 2000). Thus, the mere fact that the specification discloses "at least two" proximal pairs of holes does not show, in light of the evidence adduced at trial, that the applicant did not possess an invention with only one proximal pair of holes. Rather, the court finds that the facts of this case are similar to the situation in Lampi, where a specification describing a flourescent lamp with two identical housing half-shells was held to provide support for patent claims encompassing non-identical half-shells, when the shape of the half-shells was "not critical to the invention." Id.

Applicable authority stresses the "fact-specificity" of the written-description issue and, therefore, the limited precedential value of decisions in that area. See, e.g., Vas-Cath, 935 F.2d at 1562; In re Driscoll, 562 F.2d 1245, 1250 (C.C.P.A. 1977). Even so, the court does not find the authority cited by Synthes persuasive. In In re Barker, 559 F.2d 588 (C.C.P.A. 1972), the court found that a disclosure of a prefabricated roof panel large

enough to hold eight shingles did not adequately support a subsequent claim covering a smaller panel containing six roof shingles. The court rejected the argument that an eight-shingle pattern inherently encompassed a pattern using fewer shingles because the panel size and the number and pattern of shingles were uniquely tied to each other and the specification disclosed a repeated pattern of eight shingles. Id. at 593. Thus, because the minimum number of shingles was an integral part of the described invention, a pattern consisting of fewer shingles was not inherently disclosed. Likewise, in In re Jones, 10 Fed. Appx. 822, 2001 WL 267053 (Fed. Cir. 2001), a specification describing open-ended helical channels on the surface of dental implants was held not to describe sufficiently helical channels with closed ends, in part because the applicant's description suggested that "closing the helical channel ends would cause his invention not to work."[7] Id. at *5.

In this case, Synthes has not sufficiently shown that the second proximal pair of holes constitutes an integral element of the invention described in the '917 application or otherwise provides a functional advantage over prior art. The two-pair device is merely one species of a broader genus including devices with one and two pairs of holes. Thus, the '406 and '663 patents are entitled to the filing date of the '917 application, and Synthes has not shown that the patents in suit should be held

[7] The Jones decision also states explicitly that it is not to be cited as precedent.

invalid.

2. Enablement

A patent specification must disclose the claimed invention in a manner clear enough "to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the [invention]." 35 U.S.C. § 112. Synthes sought to show at trial that the patents in suit are not sufficiently specific to enable one skilled in the art to practice the claimed invention. Synthes offers the testimony of Anthony James to the effect that "a good deal of experimentation would be required to construct a device according to the Brumfield patents." (Tr. 1839:9-20). In particular, Synthes cites evidence that the inventor, David Brumfield, tested the Recon Nail for several years and determined optimal design and structural characteristics necessary to practice the best mode of the claimed inventions, but failed to disclose those specifications, in violation of 35 U.S.C. § 112.

"[A] patent need not teach, and preferably omits, what is well known in the art." Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986). The specification fails the enablement requirement only if practicing the invention would require "undue experimentation." In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). Smith & Nephew offered evidence showing that the general technique for treating a fracture through sliding compression, including anatomic and material constraints, was well

known in the industry. (Tr. 3072:15-3073:22) A failure to include numerical specifications for achieving sliding compression, therefore, is not a violation of the enablement requirement. Further, James testified that the level of experimentation required to practice the claimed inventions would not be undue. (Tr. 3502:7-3503:17). Thus, Synthes has failed to show by clear and convincing evidence that the patent is invalid for failure to enable one skilled in the art to practice the claimed invention.

3. Best Mode

A patent specification must "set forth the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112. Synthes sought to show that Brumfield, the inventor of the patents in suit, had finalized design specifications including materials, sizes, and angles, before he submitted the '917 application. (TX 110; Tr. 1822:3-11, 1822:25-1823:2, 1825:10-1826:9, 1827:2401828:2, 1828:19-21). Synthes contends that failure to disclose the specifications for the Recon Nail in the '917 application amounted to a failure to satisfy the best-mode requirement of 35 U.S.C. § 112. "Patent invalidity for failure to set forth the best mode requires that 1) the inventors knew of a better mode of carrying out the claimed invention than they disclosed in the specification, and 2) the inventors concealed that better mode." Engel Industries, Inc. v. Lockformer Co., 946 F.2d 1528, 1532 (Fed. Cir. 1991).

Synthes has not shown by clear and convincing evidence that

Brumfield concealed the best method for practicing the '917 invention. Brumfield testified to his belief at the time of invention that those skilled in the art of femoral fracture fixation would be familiar with the anatomic geometry of the femur, the prior art devices, the function they played in treating fractures, the readily available materials to use in making the device, the tradeoffs between size of the screw, hole, and nail, and the type and size of screw/nail. (Tr. 3073:25-3075:22). Additionally, the production drawings that he had made at that time were sent to patent counsel to be included in the supporting documentation for the patent application. (TX 168; Tr. 2961:11-2962:9). That the '917 application did not disclose the precise specifications eventually used for the production of the Recon Nail does not mean that the applicant concealed the best mode for practicing his invention. See Engel Industries, 946 F.2d at 1532 ("a patent disclosure is not a 'production specification,'... and ... technical details apparent to a person of ordinary skill need not be included in the patent specification"). Thus, Synthes has not established that the '917 specification concealed a better mode of practicing Brumfield's invention.

B. 35 U.S.C. § 102-03 (Novelty and Obviousness)

In addition to its objections to the '917 specification, Synthes contends that the '663 and '406 patents are invalid because their claims are anticipated or rendered obvious by the prior art. "A party asserting that a patent claim is anticipated under 35

U.S.C. § 102 must demonstrate, among other things, identity of invention." Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1565 (Fed. Cir. 1992)(internal quotations omitted). Anticipation under 35 U.S.C. § 102 requires that a single piece of prior art contain each and every limitation of the patented invention either expressly or inherently. Transclean Corp. v. Bridgewood Services, Inc., 290 F.3d 1364, 1370 (Fed. Cir. 2002).

Where no single piece of prior art contains every limitation in an issued patent, the patent may still be invalidated as obvious under 35 U.S.C. § 103, by reference to multiple pieces of prior art. See Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1267 (Fed. Cir. 1991). In determining obviousness, the invention must be considered as a whole, without the benefit of hindsight, and the claims must be considered in their entirety. See Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721 F.2d 1563, 1567 (Fed. Cir. 1983); W.L. Fore & Assocs. v. Garlock, Inc., 721 F.2d 1540, 1551 (Fed. Cir. 1983). "Focusing on the obviousness of substitutions and differences, instead of on the invention as a whole, is a legally improper way to simplify the difficult determination of obviousness." Gillette Co. v. S.C. Johnson & Son, Inc., 919 F.2d 720, 724 (Fed. Cir. 1990); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1383 (Fed. Cir. 1986). Synthes sought to prove that the patents in suit were anticipated or rendered obvious by one or more of the following inventions.

1. Huckstep Nail

Synthes argues that two different versions of the invention known as the Huckstep Nail anticipate and/or render obvious the patents in suit. Both versions of the Huckstep Nail are roughly square in cross-section, with rounded edges. Both have multiple transverse openings along their length for the placement of screws. The proximal portions of both Huckstep Nails have four oblique smooth openings that are set at an angle of about 130 degrees to the longitudinal axis of the rod and are directed towards the femoral head when implanted in the intramedullary canal. (TX 23; Tr. 1081:5-17, 2477:16-2478:1). Both the standard and bulbous Huckstep Nail use partially threaded titanium lag screws which are inserted through the oblique openings in the head of the intramedullary rod, through the femoral neck and into the femoral head. (TX 26, 27; Tr. 1081:5-17, 3215:13-25). Both versions of the Nail, as well as the lag screws used with them, are made from a titanium alloy. (TX 27; Tr. 2479:24-2483:9).

a. Standard Huckstep

The Standard Huckstep was included in the Downs Surgical Brochure and considered by the Patent Office during prosecution of the '406 and '663 patents. The Huckstep Nail was designed for "rigid fixation," to enable early patient weight-bearing, and none of the available Huckstep literature describes sliding

compression.[8] (See TX 24, 25, 26, 27, 28; Tr. 316:14-21, 1352:21-1353:5, 1357:17-25, 1363:23-1364:3, 2169:19-24). The shanks of the 4.5 mm lag screws in the Huckstep Nail are slightly narrower than the holes through which the screws are threaded. (TX 25; Tr. 2300:20-2301:7). Thus, unlike the patents in suit, there is no closely conforming fit that provides for continuous contact, as would be necessary to achieve sliding compression. Therefore, the downward forces exerted on the femoral head create a risk that the screw will bind or bend, rather than slide in a direction parallel to the proximal openings. (Tr. 2172:7-24, 3018:24-3019:11).

Synthes cites studies of the Huckstep Nail that show certain instances in which the treated fractures did, in fact, compress in a direction parallel to the 4.5 mm lag screws, as would occur with a device intended to achieve sliding compression. These few instances, however, do not show that the compression was caused or aided by the physical structure of the Huckstep Nail. Testimony of a surgeon who had experience using the Standard Huckstep to treat femoral fractures indicates that he experienced varus malunion[9] in a significant percentage of his cases and found that the 4.5 mm screws moved excessively within the proximal openings. (TX 25; Tr.

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[8] Synthes is correct in arguing that actual use of the phrase "sliding compression" is not dispositive, as it is unclear whether that phrase has been used to describe any products other than those marketed by Smith & Nephew. The cited literature, however, does not describe the physical process by which the proximal screw is intended to slide through the intramedullary rod, allowing femoral bone fragments to be squeezed together.

[9] "Varus malunion" is a condition in which weight-bearing forces cause the femoral head to heal in an abnormally low position. Sliding compression is a technique that helps to prevent varus malunion.

2300:20-2301:7). Given the evidence adduced at trial, Synthes has not shown that the fractures healed in the manner normally achieved by sliding compression because of the configuration of the Standard Huckstep. See Eibel Process Co. v. Minn. & Ontario Paper Co., 261 U.S. 45, 66 (1923)("accidental results, not intended and not appreciated, do not constitute anticipation").

Synthes has, therefore, failed to show by clear and convincing evidence that it would have been obvious to modify the Standard Huckstep to achieve sliding compression. The invention and accompanying literature made no suggestion of sliding compression as an objective or possible use of the Huckstep invention. Although sliding compression was a known method of treating certain femoral fractures, the Huckstep Nail did not employ sliding compression to treat femoral fractures. Thus, the court cannot conclude that the Standard Huckstep anticipates or renders obvious the technique of sliding compression claimed in the patents in suit.

In addition to sliding compression, the patents in suit provide for an intramedullary rod that is longitudinally hollow, or "cannulated." The Huckstep Nail is solid, with transverse holes throughout its length. (TX 23). Synthes argues that, in addition to the modifications necessary to achieve sliding compression, it would have been obvious to one skilled in the art to cannulate the Standard Huckstep. Cannulation of an intramedullary rod is necessary to insert the rod over a guide wire, as part of the

"closed" insertion technique, which was well known in the industry when the patents in suit were filed and when Dr. Huckstep invented the Nail. (Tr. 1144:22-1145:8, 2548:18-2549:3, 2554:25-2555:20). It was believed that cannulation of the Standard Huckstep, however, would have significantly weakened the device, and the invention and accompanying literature stressed the importance of strength for early patient weight-bearing. (Tr. 274:25-2167:3, 483:3-484:27, 2159:22-2160:13, 2166:25-2167:20). Because of the numerous transverse holes, cannulation also carried the risk that the rod would bend or break more easily at the site of one of the holes. (Tr. 484:8-24, 2159:22-2160:13, 2163:14-2164:5, 2768:17-2770:2, 3267:9-3269:10).

Considering this information and viewing each invention as a whole, Synthes has not demonstrated that it would have been obvious to one skilled in the art to modify the Standard Huckstep Nail to achieve sliding compression. In important respects, the structure and objectives of the Standard Huckstep suggest against the modifications suggested by Synthes, and there is significant evidence that those modifications would have been undesirable or unfeasible. Thus, the patents in suit are not anticipated or rendered obvious in light of the Standard Huckstep Nail.

b. Bulbous Huckstep

The Bulbous Huckstep Nail is a variation on the Standard Huckstep Nail. The Bulbous Huckstep has an enlarged proximal portion to accommodate larger openings for wider lag screws. (Tr.

1357:7-10). Although the lag screws used with the Bulbous Huckstep have a wider threaded portion, their shank is of equal or smaller size than those used in the Standard Huckstep. (TX 27; Tr. 318:10-15, 1354:24-1355:2, 1356:1-6, 2183:18-24, 3253:21-3255:1). Thus, the same risk of binding or bending is present in the Bulbous Huckstep. Additionally, the same factors that make cannulation of the Standard Huckstep undesirable apply to the Bulbous Huckstep. (See TX 27). The patents in suit, therefore, are not anticipated or rendered obvious by the Bulbous Huckstep Nail.

2. Zickel Nail

The Zickel Nail is a solid (non-cannulated) intramedullary rod with a generally square lateral cross section. The Zickel Nail includes a "tri-flange" cross nail that extends into the femoral neck. The tri-flange nail has no helical threads; it is held in position using a locking set screw to prevent it from backing out. (TX 34; Tr. 421:9-11, 1243:15-19, 1281:16-22, 1788:19-1789:1). In addition, the Zickel Nail is curved in such a way as to make it difficult to insert into and remove from the femoral shaft. (Tr. 1263:20-1263:25, 1264:1-5, 2816:24-2817-20).

a. Original Zickel Nail

The Zickel Nail's locking screw prevents the cross nail from sliding. The device, therefore, is indicated only for subtrochanteric fractures. It was not intended to be used in treating intertrochanteric or femoral neck fractures. (Tr. 2344:25-2345:14). Further, the unique curvature of the Zickel Nail

presented potential difficulties for cannulation. (Tr. 499:25-500:14, 2649:23-2650:16). These facts clearly suggest against the modifications proffered by Synthes. Thus, the original Zickel Nail does not anticipate or render obvious the patents in suit.

b. Dennis Modified Zickel Nail

Dr. Robert Dennis modified the Zickel Nail by replacing the triflange cross nail with a standard compression lag screw, to allow sliding compression of intertrochanteric and femoral neck fractures. (Tr. 1147:15-19, 1148:14-1149:4, 2651:5-21). Unlike the '406 and '663 inventions, Dennis intended for a sleeve to surround the proximal lag screw, mimicking the structure of the conventional Richards compression screw. Although Dennis experimented on cadavers with a prototype that did not contain the sleeve (and thus maintained continuous contact between the screw and the proximal hole as provided in the patents in suit), all of the devices that were implanted in actual patients contained the sleeve, because Dennis felt that a sleeve was necessary to permit sliding of the proximal lag screw. (Tr. 2415:17-2416:8).

That the inventor of the Dennis Modified Zickel Nail experimented with a version of the device that worked without a sleeve and ultimately decided against using the non-sleeve version suggests that elimination of the sleeve was not a desirable modification. Further, Dennis's modification contains the same angular curvature as the original version of the Zickel nail, making the additional element of cannulation no more obvious or

desirable than for the original Zickel Nail. (TX 76; Tr. 1249:25-1250:8, 1277:6-9, 3035:20-3036:5). Thus, Synthes has failed to show by clear and convincing evidence that the patents in suit were anticipated or rendered obvious by either version of the Zickel Nail.

3. Marcus Patent

The Marcus patent discloses a cannulated intramedullary rod having a head with a sidewall thickness greater than the sidewall thickness of its stem. The disclosed device contains pairs of openings whose axes cross to allow screws to be inserted in a variety of different directions. (See TX. 77). The Patent Office considered the Marcus patent during prosecution of the '663 and '406 patents. The Patent Office initially rejected the '663 application in light of the Marcus patent, and certain amendments were made specifically to overcome the Marcus reference. The '663 applicant had a conversation with the Examiner on February 21, 1992, after which the Examiner noted that "Applicant has agreed to amend the scope of the claims to more fully describe the proximal portion to emphasize the coaxial bores and thickened wall portion for better sliding." (Undisputed Facts 6.46). The amendments made in response to the Examiner's statement emphasize the thickened head portion of the intramedullary rod in the '663 patent. (U.F. 6.49).

The device disclosed in the Marcus patent possesses holes, each of which is able to accept multiple screws positioned at

different angles. Because each hole must accommodate multiple screw paths, the screws for insertion into the femoral head would be supported by a "knife edge," rather than a smooth surface that conforms with the cross section of the proximal screw. (TX 20, Col. 8:28-32; TX 21, Col. 8:21-25; Tr. 3045:16-3046:25, 3298:11-21). This configuration is not conducive to sliding compression and fails to conform with at least element 1(c) of the '663 patent and element 1(g) of the '406 patent.

The specification of the Marcus patent discloses a method to achieve conformity between the opening in the rod and the screw by reaming the opening in the direction of the axis along which the screw will be inserted. (TX 77, Col. 8:12-17; Tr. 2566:16-2568:1). That the specification anticipated the need for such a modification demonstrates that the required feature does not inhere in the structure of the device. Rather, the need to accommodate screws from multiple angles prevents the Marcus device from possessing proximal holes with smooth openings that closely conform with the screws angled into the femoral head. Because a multiple-screw feature is an integral element of the device, the Marcus patent teaches away from modification to conform with the asserted patents. See Gillette Co. v. S.C. Johnson & Son, Inc., 919 F.2d 720, 724 (Fed. Cir. 1990). Thus, viewing the asserted claims as a whole, Synthes has not offered clear and convincing evidence that they are anticipated or rendered obvious by the Marcus patent.

4. German Utility Model

Smith & Nephew concedes that the German Utility Model ("Gebrauchsmuster") shows every element of claim 1 of the '663 patent and claim 1 of the '406 patent, but argues that it is not prior art for purposes of this lawsuit. Neither party disputes that the German Utility Model became public for purposes of priority on October 9, 1986. Smith & Nephew contends that the date of invention was no later than August 12, 1986, and that the patents in suit should be entitled to priority as of that date. To establish its existence as prior art, Synthes must show by clear and convincing evidence that the German Utility Model was made public before Brumfield's invention date. See Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1578 (Fed. Cir. 1996); Loral Fairchild Corp. v. Matsushita Electric, 266 F.3d 1358, 1360 (Fed. Cir. 2001)(reversing grant of summary judgment where district court had failed to consider plaintiff's evidence that invention was reduced to practice before patent was issued and before allegedly invalidating reference was published).

An inventor can establish priority over a reference published before he filed his patent if it is established that he "was first to conceive the invention and that [he] exercised reasonable diligence in later reducing that invention to practice." Murkar, 79 F.3d at 1577 (quoting Price v. Symsek, 988 F.2d 1187, 1190 (Fed. Cir. 1993)). Both parties agree that the invention had been constructively reduced to practice by December 30, 1986, when

Brumfield filed the '917 application. See, e.g., Stevens v. Tamai, 366 F.3d 1325, 1330 (Fed. Cir. 2004)(citing Hyatt v. Boone, 146 F.3d 1348, 1352 (Fed. Cir. 1998)). The testimony of a prior inventor may be corroborated by physical records, other evidence made at the time of the earlier invention, or oral testimony of someone other than the inventor.[10] See Sandt Technology, Ltd. v. Resco Metal & Plastics Corp., 264 F.3d 1344, 1350-51 (Fed. Cir. 2001); Woodland Trust v. Flowertree Nursery, Inc., 148 F.3d 1368, 1371-73 (Fed. Cir. 1998).

Despite Synthes's contention that Smith & Nephew has offered "no evidence" about how or when Brumfield's invention was reduced to practice, the evidence offered at trial suggests reasonable diligence in prosecuting the patent application. After sending his record of invention to patent counsel on August 26, 1986, Brumfield met with patent counsel, had conversations on the telephone with patent counsel, and reviewed the patent application and made comments on it. (Tr. 2962:24-2963:2, 2963:2-3, 2963:20-21). Synthes introduced no evidence that Brumfield abandoned or ceased prosecuting the '917 patent from August 26 to December 30, 1986. Thus, Synthes has not shown by clear and convincing evidence that the German Utility Model is anticipatory prior art.

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[10] The cited authority on corroborating evidence appears to govern cases where an alleged infringer attempts to introduce evidence of prior invention to challenge a duly issued patent. Because the situation is reversed in this case, the requirements for corroborating evidence are arguably lower. Nevertheless, the court will consider corroborating evidence of Brumfield's prior invention and reasonable diligence.

5. Marino Patent

The Marino patent discloses a femoral fracture fixation assembly including an intramedullary rod, a side plate resembling that included in a compression hip screw assembly, and a pair of smooth-shafted screws that extend through oblique holes in the extension piece and into the head of the femur. (TX 53, Column 2:31-67). The Marino patent discloses two differently sized oblique openings through the intramedullary rod extension and, correspondingly, two screws of different diameter that pass through the openings. (TX 53, Column 2:64-67; Tr. 1161:12-1162:13, 1165:11-24, 2506:18-2509:1). Synthes does not appear to argue, nor does the court find, that the Marino patent itself anticipates or renders obvious the patents in suit. The Marino patent discloses an intramedullary rod combined with a side plate, the elimination of which was one innovation of the patents in suit, and the claims were specifically amended to overcome the Marino reference. (U.F. 6.47-48). Further, Synthes has not identified, nor can the court locate, a specific feature in the Marino reference that would, in combination with other references, anticipate or render obvious the disputed claims.

6. Other Considerations

Carefully considering all of the evidence admitted at trial, the court is unable to conclude that Synthes has offered clear and convincing evidence under any of the proffered legal theories sufficient to overturn the Patent Examiner's finding of validity.

In determining the issue of obviousness, "[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966). At trial, Smith & Nephew offered evidence of the market need for the products sold under the patents in suit, the commercial success of those products, and the licenses taken under the patents. (Tr. 328:2-330:16, 1376:18-1377:5, 3061:19-3062:3, 3345:17-3346:6). Although Synthes has effectively questioned the relevance of the licenses taken and portions of the revenues generated, the overall commercial success of the product line in which the patented products played an integral role suggests the patents' novelty and lack of obviousness, in light of the above analysis. The court, therefore, finds the patents in suit valid and enforceable.

III. Infringement

At trial, Smith & Nephew sought to prove that the long and short versions of Synthes's PFN and TFN products infringe the '406 and '663 patents. "The party alleging infringement ... has the burden of proving infringement by a preponderance of the evidence." Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1054 (Fed. Cir. 1988). A patent is infringed if one or more claims it recites is infringed. Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc., 261 F.3d 1329, 1336 (Fed. Cir. 2001). A patent claim

is infringed literally if every element it recites is found in the accused product or process. Rohm and Haas Co. v. Brotech Corp., 127 F.3d 1089, 1092 (Fed. Cir. 1997); Cole v. Kimberly-Clark Corp., 102 F.3d 524, 532 (Fed. Cir. 1996). If a product does not meet the literal language of each claim element, it can still infringe under the "doctrine of equivalents." For mechanical devices, like those at issue in this case, infringement would require that an element in the accused product "perform substantially the same function in substantially the same way to obtain substantially the same result" as the allegedly infringed claim element. Graver Tank & Mfg. Co. v. Line Air Products Co., 339 U.S. 605, 608 (1950); see also Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co., 520 U.S. 17, 39-40 (1997)(holding that the Graver "triple identity" test is suitable for applying the doctrine of equivalents to mechanical devices).

Synthes's TFN product consists of an intramedullary rod (TX 1, 2, 3) that supports a cross-member called the Helical Blade (TX 12, 12B). The intramedullary rod of the TFN includes a wider upper portion and a narrower lower portion designed to be implanted in the medullary canal of the femur. (U.F. 6.53). The Helical Blade is inserted at an angle into the head of the femur. The TFN is intended to permit sliding compression of certain femoral fractures, including intertrochanteric fractures. (U.F. 6.52; Tr. 643:16-23, 1555:11-15.) The TFN rod is cannulated along its length and has an oblique opening with a smooth surface, permitting sliding compression. (Tr. 638:7-11.)

In the 11 mm and 12 mm versions of the TFN, only the transitional portion of the head wall is thicker than the stem wall. (Tr. 763:15-764:22; TX 55.) In other versions, both the transitional and non-transitional portions of the head are thicker than the stem. The following versions of the TFN are "fluted," meaning that the outer diameter of a cross section of the stem is variable: 1) all 235 mm length versions of the "short" TFN rod, and 2) the 11 and 12 mm versions of the "long" TFN rod. (TX 17; TX 13; TX 3, respectively).

Synthes's PFN product (TX 17, 99) is an intramedullary implant designed to treat fractures of the femur, including intertrochanteric fractures. (U.F. 6.86.) The PFN includes an intramedullary rod portion that is inserted into the intramedullary canal of a femur and two screws that pass through the intramedullary rod and into the femoral head. Two openings are provided at the upper portion of the intramedullary nail to accommodate the two screws that extend through it at an oblique angle. (TX 17, 99; U.F. 6.73.) The PFN is indicated for treating intertrochanteric fractures. (U.F. 6.8; TX 18 at 3081.) PFN Model Numbers 473.130, 473.130.211, 473.121, 473.131.211, 473.132, and 473.132.211 are solid and non-cannulated. Smith & Nephew concedes that these devices cannot infringe the '663 patent, which requires a cannulated rod in all claims at issue. (Smith & Nephew Proposed Findings of Fact ¶ 90.)

The court will examine the infringement issues under the

framework in which they were presented at trial.

A. Whether the TFN Helical Blade Is a Screw

Synthes contends that the TFN product does not practice claim 1, and other dependent claims, of the '663 patent because the Helical Blade inserted into the femoral head is not a "first screw for insertion." Synthes contends that the TFN does not practice claim 1 of the '406 patent, and other dependent claims, for the same reason. At the Markman hearing, Synthes argued that the patent term "screw" should be confined only to those devices that are inserted into the object medium by a torsional, or twisting, force. This definition would not apply to the Helical Blade, which is driven, or hammered, into place in the femoral head. The court rejected that argument, however, concluding that it is the physical structure, rather than the method of insertion, of a device that determines whether it is a "screw" claimed by the patents in suit. The patent phrase "first screw" was interpreted to mean "a generally cylindrically-shaped simple machine of the inclined plane type, at least a portion of which is threaded."

The Helical Blade of the TFN serves the function of engagement and support of the femoral head, which is also served by the "first screw for insertion" in the asserted patents. It extends through the oblique opening in the proximal portion of the intramedullary rod and up into the femoral head. (TX 1-4, 12). Rather than traditional screw threads that wind a nearly horizontal spiral up the shaft of the screw, the Helical Blade possesses four threads,

each of which is uniquely structured and has a more vertical (steeper) pitch.

The top thread of the Helical Blade starts with no height at the tip of the device and gradually increases in height as it moves from the tip to the distal end of the shaft. The taper of the top thread reduces the potential for cut-out because there is no sharp edge directed toward the top of the femoral head. (TX 12, 91; Tr. 1205:7-17, 1604:3-6, 1477:10-1478:4). The two side threads provide a horizontal, paddle-like surface to carry loading and resist cut-out. These two threads increase in thickness as they approach the shaft of the device to aid in transferring loads to the shaft of the Helical Blade. (TX 12, 91; Tr. 1478:5-24, 1604:6-17). The bottom thread of the Helical Blade has a uniform thickness and height along its length. It provides additional surface area for engagement of bone in the head of the femur and contributes to the overall bending strength and rotational stability of the Helical Blade. (TX 12-13, 91; Tr. 1478:25-1479:17, 1604:18-22). Unlike a traditional lag screw, the zero-height top thread and the two side threads form a flat plane to receive loading, such that there are no sharp edges against the loading force. This characteristic helps to prevent the device from cutting out of the femoral head in patients with softer bone. (TX 92-93; Tr. 787:1-788:1, 1482:21-1483:10, 1610:10-1611:11).

Although Synthes has submitted credible evidence that the TFN Helical Blade constitutes an improvement over the traditional lag

screw included in the inventions sold under the patents in suit, the issue before the court is whether the TFN Helical Blade qualifies categorically as a "screw" as claimed by the patents in suit. The physical structure of devices actually sold under the patents does not limit the meaning of the claim language. See Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1057-58 (Fed. Cir. 1988) ("Adding features to an accused device will not result in noninfringement if all the limitations in the claims, or equivalents thereof, are present in the accused device"). After careful consideration of all of the evidence admitted at trial, the court concludes that the TFN Helical Blade is "a generally cylindrically-shaped simple machine of the inclined plane type, at least a portion of which is threaded."

Synthes's primary argument directed at the claim language is that the Helical Blade is not a "simple machine of the inclined plane type" because the pitch of the threads is such that it requires less force to drive the Helical Blade into the femoral head than it would to rotate or twist it into the femoral head. Because a simple machine is a device used to make work easier by providing a mechanical advantage, Synthes contends that the threads, or blades, are not configured so as to allow the Helical Blade to function as a simple machine of the inclined plane type. (Tr. 1440:209).

Dr. Eric Gozna testified on behalf of Synthes that an inclined plane makes work easier by allowing an object to be moved a given

vertical distance using less force than would otherwise be necessary. (TX 85; Tr. 1440:10-1441:25). A screw is a simple machine of the inclined plane type because the thread of a screw is an inclined plane wrapped around a cylindrical shaft. (TX 85; Tr. 1442:17-1443:9). The pitch of a screw is the distance between the tips of the screw thread. The greater the pitch, the steeper the inclined plane, and the less efficiently the device will work as a simple machine of the inclined plane type. (TX 85; Tr. 1443:5-23). As a screw is inserted into a material (in this case, bone), the object material "rides up" the inclined plane, e.g., the screw thread. The shape of the inclined plane (screw thread) is capable of converting a torsional (or "horizontal") input force into an axial (or "vertical") force advancing the screw into the material. (TX 85; Tr. 1441:1-22). As the thread pitch is increased (i.e., as the inclined plane gets steeper), the mechanical advantage of applying a torsional force diminishes, until it requires less force to advance the screw using a vertical ("driving") force than using a horizontal ("twisting") force. (TX 85; Tr. 1444:23-1446:7).

Synthes's foregoing description of the manner in which a screw functions as a simple machine of the inclined plane type is accurate. The court cannot accept, however, the argument or testimony that a screw ceases to be a "simple machine of the inclined plane type" when the screw threads obtain a steepness at which it is easier to drive the screw than to twist the screw. Using the description offered by Synthes and accepted by the court, an inclined plane does not cease to be an inclined plane because

its steepness results in a failure to achieve some predetermined level of efficiency. Offering a distinction between the respective forces required in driving and twisting a screw is a sophisticated way of making the argument that was rejected in the Markman hearing: that a "screw" is twisted into place and a "nail" is driven into place. The mechanical advantage provided by an inclined plane is measured by comparing the force *parallel to the inclined plane* with the purely vertical force required to overcome gravity. (See TX 85, Demo. 3-4)(emphasis added). Mechanical advantage is not measured, as Synthes contends, only by comparing a purely horizontal, or in the case of a screw, torsional, force to a purely vertical force.

The patent's definition of the term "screw" imposes no limitations on the manner or ease with which the screw must be inserted. (Markman Order at 14; Tr. 2984:7-2985:2, 2995:16-2996:19). Two of Synthes's experts conceded that they were unaware of any scientific literature, reference, or treatise to support their opinions that the fundamental point of distinction between a nail and a screw is whether the pitch of the threads makes it easier to hammer or twist into the object material. (Tr. 1231:3-14, 1510:25-1512:1). More importantly, the patents in suit appear to make no attempt to distinguish a "nail" from a "screw."[11] See, e.g.,

[11] The specification of the '663 patent states that "the apparatus may further include means, such as a nail, screw or bolt, associated with the rod for preventing rotation of the head of the femur relative to the first screw." Column 3:30-39. Although this language separately references a "screw" and a "nail," it does not refer to the disputed "first screw for insertion," give guidance as to what characteristics may distinguish a screw from a nail, or

Phillips v. AWH Corp., 415 F.3d 1303, 1320 (Fed. Cir. 2005)(rejecting the "presumption" in favor of dictionary definitions announced in Texas Digital Systems, Inc. v. Telegenix, Inc., 308 F.3d 1193 (Fed. Cir. 2002), as giving inadequate weight to the role of the specification in interpreting claim language).[12] If the term "screw" were meant specifically to disclaim similar prior art that employed a nail for insertion into the femoral head, Synthes's proffered distinction would be more persuasive. The evidence introduced at trial pertaining to "spiral nails" and "drive screws" shows, if anything, that the terms "screw" and "nail" may overlap, that they are not mutually exclusive. (See TX 42-43; Tr. 2996:20-2997:8, 3124:8-14). The question before the court is only whether the Helical Blade qualifies as a screw as defined in the '406 and '663 patents.

The Helical Blade qualifies as a "screw" as defined by the court and claimed by the patents in suit. An examination of the device clearly shows that it is "generally cylindrically shaped." (TX 12). The helical threads ease the insertion of the Helical Blade into the head of the femur and provide a mechanical advantage in retaining engagement of the femoral head when bone fragments are squeezed together. (Tr. 1239:25-1240:13, 1418:25-1419:5, 1498:13,

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suggest that "screw" and "nail" are mutually exclusive categories.

[12] The Phillips decision emphasizes that dictionary definitions should not be used to "divorc[e] the claim language from the specification." Phillips, 415 F.3d at 1324. Although the Markman opinion in this case relied on dictionary definitions for guidance in construing certain terms, the court employed extrinsic evidence only to decide what the disputed claim language means to one skilled in the art, within the specific context of the patents in suit.

1498:25-1499:13). Thus, the TFN Helical Blade qualifies as "a generally cylindrically-shaped simple machine of the inclined plane type, at least a portion of which is threaded."

B. Whether the "Fluted" Devices Have a Uniform Stem Wall Thickness

Claim 1(b) of the '663 patent discloses an intramedullary rod with a sidewall "having a first, generally uniform smaller wall thickness defining the stem, and a second, larger wall thickness defining the head." The court has defined the phrase "first, generally uniform smaller wall thickness defining the stem" to mean "the wall thickness of the stem is thinner than the wall thickness of the head and that thickness does not vary significantly; the thinner wall and the uniformity define the stem as distinct from the head." Several of Synthes's devices have a "fluted" stem portion, meaning that the outer circumference of the stem resembles that of the bit of a Phillips head screwdriver, rather than being perfectly cylindrical.[13] The fluted devices are as follows 1) all 240 mm length versions of the "standard" PFN rod, 2) all 235 mm length versions of the "short" TFN rod, and 3) the 11 and 12 mm versions of the "long" TFN rod. (TX 17; TX 13; TX 3, respectively).

Synthes claims that the fluted versions of the TFN and PFN do not practice claim 1(b) of the '663 patent. The court agrees. The fluted rods perform three functions not achieved by more

[13] This analogy is not perfect. The fluted devices have six outer "points" along the circumference of the stem, where a Phillips screwdriver has only four.

traditional cylindrical rods: 1) reduced stiffness, 2) improved endosteal blood supply, and 3) decreased rotation of the rod within the bone canal. (Tr. 634:25-635:15, 1642:14-1643:8). More importantly, the fluted stem walls do not have a generally uniform thickness; rather, their thickness varies significantly. The 235 mm length TFN rods have variances in stem wall thickness ranging from 50% (between 2.7 mm and 1.8 mm) to 140% (3.25 mm to 1.35 mm). (TX 2, 45; Tr. 446:4-16; Pretrial Stip. 6.63). The 11 mm and 12 mm versions of the long TFN rod have variances in stem wall thickness ranging from 25% (3.2 mm to 2.55 mm) to 55% (3.25 mm to 2.1 mm). (TX 3, 45; Pretrial Stip. 6.68). An examination of the 240 mm version of the PFN shows that its circumferential variance in stem wall thickness is similar to that of the 11 mm and 12 mm versions of the long TFN. The foregoing variances demonstrate that the stem wall thickness of the fluted versions of the TFN and PFN are not uniformly thick along their circumference so as to practice claim 1(b) of the '663 patent. (Tr. 1642:3-13, TX 45). Further, the fluted versions of the PFN and TFN vary in stem wall thickness along their length. Each of the devices has a fluted and non-fluted portion of the stem. In particular, the variation in wall thickness between the unfluted and fluted portions along the length of the stem of the fluted TFN and PFN rods is between 25% and 140%. This variation is significant and inconsistent with claim 1(b) of the '663 patent. (Tr. 445:19-447:18). Thus, the fluted TFN and PFN rods do not infringe that patent.

C. Whether Certain Versions of the TFN Have a "Larger Wall Thickness Defining the Head"

The '663 patent claims an intramedullary rod with "a second, larger wall thickness defining the head." (Column 8:12-14.) Similarly, claim 9 of the '406 patent recites a treatment method using an intramedullary rod wherein "the side wall of the rod is thicker at the head than the side wall of the rod at the distal stem." (Column 8:36.) The court has interpreted the limitation in claim 1 of the '663 patent to mean "the wall thickness of the head is thicker than the wall thickness of the stem; the thicker wall defines the head as distinct from the stem." (Markman Op. at 11.) The head of the intramedullary rod is defined as the "[u]pper portion of the intramedullary rod extending from the end closest to the hip to the stem and includes any transitional wall thickness leading up to the stem." (Markman Op. at 11.) Smith & Nephew sought to show at trial that every version of the TFN infringed this element of the patents in suit.

The transitional portion in the head of every version of the TFN rod is thicker than the corresponding stem wall. In its prior summary judgment order, the court rejected Smith & Nephew's argument that the greater thickness in this transitional portion alone made the TFN rods infringe the patents in suit, instead holding that there was an issue of material fact about which portion or portions of the head wall were required by the patents in suit to be thicker than the stem wall.

In describing the disadvantages of the prior art, the

specification states that "[t]here is not sufficient mechanical support to allow usage of the locking screw in the direction towards the femoral head because the second pair of coaxial holes weaken the nail when loaded in that direction." U.S. Patent No. 5,167,663, Column 2:41-45. The application that became the patents in suit was initially rejected in light of prior art, particularly the Marino patent. After an interview that occurred on February 21, 1992, the Examiner noted that "Applicant has agreed to amend the scope of the claims to more fully describe the proximal portion to emphasize the coaxial bores and thickened wall portion *for better sliding.*" (Petrial Stip. 6.46.)(emphasis added). The proposed claims in the '663 patent were again rejected and, after another interview, the Examiner concluded that "it appears the suggested language overcomes the prior art." (Pretrial Stip. 6.48.)

Brumfield, the applicant, thereafter filed a "Response to Final Office Action," in which claim 1 of the '663 patent was amended to require a "hollowed" intramedullary rod and to claim only an intramedullary rod with a "second, larger wall thickness defining the head." Brumfield argued that "the apparatus allows a heavier load to be carried at the top of the rod due to the thickened portion provided in the proximal head region. These advantages were discussed with the Examiner during the recent interview and have now been incorporated into the claims by these amendments. The Marino device does not provide the thickened wall portion as claimed." (Pretrial Stip. 6.49.)

Brumfield's ultimately successful argument to the Examiner

invoked his earlier statements that a thickened head wall portion would provide "better sliding." Only a thicker portion where the coaxial holes are located would provide for better sliding because the proximal screws would have more surface area on which to slide. This statement indicates that the head wall is meant to be thicker at a portion through which the coaxial holes are bored, not at the more distal transition portion between the head and stem. Thus, it appears that the "thicker portion defining the head" does not denote the transitional portion.

As noted in the order on motions for summary judgment, the claim language in the patents in suit, read within the context of the specification, is somewhat ambiguous as to which portion(s) of the head wall must be thicker than the stem wall. In such situations, the particular embodiments described in the specification are particularly instructive. See Astrazeneca AB v. Mutual Pharmaceutical Co., Inc., 384 F.3d 1333, 1340 (Fed. Cir. 2004)("the patentee's choice of preferred embodiments can shed light on the intended scope of the claims"). In the specification of each of the asserted patents, the transition portion is shown to be no thicker than the upper part of the head. (TX 20 at Fig. 3, 12; Tr. 461:23-463:6.) There is nothing in the specification or prosecution history of the '663 patent that suggests that the transition portion has or is meant to have a larger wall thickness as opposed to the upper part of the head where the screw holes are located. (Tr. 756:5-758:4.) Thus, it appears that the "greater wall thickness defining the head" describes the proximal portion

through which the holes are bored.

The evidence offered at trial further supports this conclusion. Brumfield testified that downward weight-bearing forces on the proximal screw engaging the femoral head would exert a "cantilever" force on the intramedullary rod. Thus, the portions of rod that must withstand primary forces are immediately below the proximal hole nearest the femoral head and immediately above the opposite proximal hole, not in the transitional portion of the head. (Tr. 763:15-764:8; TX 54.)

Thus, the court concludes that those versions of the TFN in which only the transitional portion of the intramedullary rod has a thicker wall than the stem do not have a "greater wall thickness defining the head" and, therefore, do not practice claim 1 of the '663 patent. Excluding the transitional portion, the head wall thickness of all versions of the TFN rod is 3.175 mm. (Tr. 763:15-764:22; TX 55.) For all 11 mm and 12 mm versions of the TFN, this wall thickness is less than the wall thickness in the stem of the rod. For the foregoing reasons, the court concludes that the 11 mm and 12 mm versions of the TFN rod do not infringe the '663 patent, and the use of those versions of the TFN to treat intertrochanteric fractures does not infringe claim 9 of the '406 patent, which describes a device in which "the side wall of the rod is thicker at the head than the side wall of the rod at the distal stem."

D. Whether the TFN and PFN Actively Compress Fractures by Means of a Bone Screw

The '406 patent claims a method of treating intertrochanteric fractures that includes the step of "compressing the fracture using the bone screw." (Column 8:17-20.) The court has interpreted this phrase to mean "squeezing together the fractured bone fragments by means of a screw." In the summary judgment order, the court concluded that this claim would cover "a compression method in which a screw is inserted into the area of a fracture without changing the position of any bone fragments, and a doctor rotates a nut around the screw to squeeze bone fragments together." (Order at 16.) At trial, Synthes requested reconsideration of this conclusion. Smith & Nephew claims that the method of using the TFN and PFN to treat intertrochanteric fractures violates claim 1(e) of the '406 patent.

At trial, Synthes reasserted the argument that it had made in favor of summary judgment: that the TFN and PFN do not practice this claim because compression does not occur simply by rotating the screw but instead requires the use of specially-designed, additional instruments. In support, Synthes points to the Recon Nail, the invention produced and sold by Smith & Nephew under the '406 patent. The only way for a surgeon using the Recon Nail to actively squeeze the bone fragments together ("active compression") is by continuing to tighten the lag screw inserted into the femoral head after the shoulder of the screw abuts the lateral cortex of the femur. (Tr. 365:23-366:23; TX 33.) The '406 specification

discloses a similar method: "A hexagonally-shaped inset 52 in the head portion permits insertion of a suitable tool for compression of lag screw 50.... A hexagonal screwdriver or any suitable tool can be used to compress lag screw 50, 250 to a desired degree." (Column 5:18-21, 7:14-16.) Once the head-portion of the screw contacts the lateral cortex of the femur, additional turning of the screw will cause the threads to draw the opposed fracture surfaces together. (Tr. 810:11-813:8, 815:23-816:21, 3086:2-3087:8.)

A patent claim will not necessarily be limited to a preferred embodiment or the particular product sold under the patent. See, e.g., Nazomi Communications, Inc. v. ARM Holdings, PLC, 403 F.3d 1364, 1369 (Fed. Cir. 2005). Nevertheless, the embodiments cited by Synthes demonstrate that the method of active compression claimed in the '406 patent is not as narrow as Synthes argues. The embodiments rely on more than the screw itself to achieve the active compression claimed by the patent, each citing the need for "a suitable tool" to turn the screw. (Column 5:18-21, 7:14-16.) The Recon Nail and the TFN and PFN, therefore, require more equipment than "just the screw" to achieve active compression. Synthes' distinction appears to be that the Recon Nail and the '406 specification anticipate active compression by rotating the screw and the TFN and PFN employ the screw[14] only as an anchoring means.

When using the TFN device, a surgeon may compress a fracture

[14] The court, above, has found that the Helical Blade is a "screw" under the '406 and '663 patents.

by twisting the Buttress/Compression Nut (TX 9) around the Blade Guide Sleeve (TX 7), which is abutted against the handle of the Helical Blade Inserter (TX 11), which is in turn abutted against the coupling screw connected to the Helical Blade. All of these items must move in order to achieve active interfragmentary compression using the TFN. (Tr. 1669:17-1670:3, 1766:21-1768:24.) The PFN uses a similar mechanism to actively compress bone fragments. That these mechanisms have more physical components than those used by the Recon Nail or a traditional compression hip screw system does not mean that they avoid the claimed step of "compressing the fracture using the bone screw." A compression mechanism in which a screw plays an indispensable role compresses the fracture "by means of a screw." This mechanism may use only an intramedullary rod, a screw, and a screwdriver, or it may, like the TFN and PFN, be more complex. Thus, using the TFN and PFN to actively compress intertrochanteric fractures practices the claimed method of "compressing the fracture using the bone screw."

IV. Conclusion

A. '406 Patent

The '406 patent claims a "method of treating intertrochanteric fractures." Use of the either of the inventions in question, therefore, for purposes other than the treatment of intertrochanteric fractures does not infringe the '406 patent.

1. TFN

After consideration of the evidence and arguments presented at

trial, the court concludes that the use of the TFN to treat intertrochanteric fractures practices all of the elements of claims 1, 2, and 3 of the '406 patent. Because they do not have "a greater wall thickness defining the head," use of the 11 mm and 12 mm versions of the TFN does not practice claim 9 of the '406 patent. Use of other versions of the TFN presented at trial infringes claim 9 of the '406 patent.

2. PFN

PFN Model Numbers 473.130, 473.130.211, 473.121, 473.131.211, 473.132, and 473.132.211 are solid and non-cannulated. Thus, they cannot infringe claim 9 of the '406 patent, which requires a "longitudinal bore surrounded by an intramedullary side wall." The court concludes that use of all versions of the PFN to treat intertrochanteric fractures practices all of the elements of claims 1-3, 5-7 of the '406 patent, and use of all but the above-described models infringes claim 9 of the '406 patent.

B. '663 Patent

1. TFN

After consideration of the evidence and argument offered at trial, the court concludes that the fluted versions of the TFN (e.g., TX 1-2) do not infringe the '663 patent because they lack a "generally uniform stem wall thickness." Likewise, the 11 mm and 12 mm versions of the TFN do not infringe because they lack a "larger wall thickness defining the head." Remaining versions of the TFN infringe claims 1-3 and 5 in the '663 patent.

2. PFN

PFN Model Numbers 473.130, 473.130.211, 473.121, 473.131.211, 473.132, and 473.132.211 are solid and non-cannulated. Thus, they cannot infringe the '663 patent, which claims a cannulated intramedullary rod. Fluted versions of the PFN – all 240 mm length "Standard" versions (e.g., TX 17) – do not infringe the '663 patent because they lack a "generally uniform stem wall thickness." Remaining versions of the PFN infringe claims 1-3 and 5 of the '663 patent.

As described above, certain of Synthes' inventions infringe the patents in suit. Therefore, the trial will proceed to the determination of damages.

So ORDERED this 26th day of August 2005.

SAMUEL H. MAYS, JR.
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT - WESTERN DISTRICT OF TENNESSEE

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